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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,561	10/15/2004	David J. Chen	LBNL-201-US	4182

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EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/511,561	CHEN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/15/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' preliminary amendment filed on 10/15/04 has been acknowledged. Claims 19-41 are pending.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 19-22, drawn to an antibody which specifically binds to an epitope defined by at least 10 amino acid sequence from human DNA-PKcs comprising a phosphorylated threonine at T2609.

Group II, claim(s) 23-26, drawn to an antibody which specifically binds to an epitope defined by at least 10 amino acid sequence from human DNA-PKcs comprising a phosphorylated serine at S2056.

Group III, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:4.

Group IV, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:5.

Group V, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:6.

Group VI, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:7.

Group VII, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:8.

Group VIII, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:9.

Group IX, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:10.

Group X. claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:11.

Group XI, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:12.

Group XII, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:13.

Group XIII, claim(s) 27-34, drawn to a method for determining the ability to a test compound to block phosphorylation of human DNA-PKcs and measuring the phosphorylation of DNA-PKcs fragment as in SEQ ID NO:14.

Group XIV, claim(s) 35-36, drawn to an isolated peptide having less than 1000 amino acids comprising SEQ ID NO:4.

Group XV, claim(s) 35-36, drawn to an isolated peptide having less than 1000 amino acids comprising SEQ ID NO:5.

Group XVI, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:16.

Group XVII, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:17.

Group XVIII, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:18.

Group XIX, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:19.

Group XX, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:20.

Group XXI, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:21.

Group XXII, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:22.

Group XXIII, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:23.

Group XXIV, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:24.

Group XXV, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:25.

Group XXVI, claim(s) 37-40, drawn to an isolated polynucleotide encoding the peptide as in SEQ ID NO:26.

Group XXVII, claim(s) 41, drawn to a method for measuring radiosensitivity of cells in a subject by measuring of phosphorylation of T2609.

Group XXVIII, claim(s) 41, drawn to a method for measuring radiosensitivity of cells in a subject by measuring of phosphorylation of S2056.

3. The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Groups I-XXVIII were found to have no special feature that defined the contribution over the prior art of Jafri et al. (Journal of Immonological Methods, vol. 251, p. 52-61) as is evidenced in LabVision DNA-PKcs Ab-1 datasheet.

Jafri et al. teach that DNA-PKcs is a subunit of DNA-PK complex and is phosphorylated in response to DNA damage. The phosphorylation results loss of protein kinase activity and disruption of DNA-PKcs from DNA-PK complex (p. 54, in particular). Jafri et al. further teach the monoclonal antibody to DNA-PKcs, clone 18-2 (p. 54) and as is evidenced by the Datasheet provided from LabVision, the epitope encompasses T2609. Therefore, the reference teachings anticipate the claimed invention of claims 19-21 and 23-25.

4. If applicant elects any one of Groups III-XIII, applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

Applicant is required to elect ONE method for determining the ability of a **specific test compound** to block phosphorylation of human DNA-PKcs as in claims 33-34 such as imidazole, thiazole, and wortmannin. These test compounds are distinct species because of their physicochemical structures and properties. Thus, each test compound represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-28 are generic for Groups III-XIII.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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